International review of the research report entitled 'Evaluation of health risks of playing sports on synthetic turf pitches with rubber granulate'

Introductory text for the RIVM website

In response to a request from the Scientific Advisory Board <link>, RIVM conducted an international review of the rubber granulate study. The scientific sounding board group that was consulted on the study on the "Evaluation of health risks of playing sports on synthetic turf pitches with rubber granulate" [link] consisted exclusively of national experts from the Netherlands. The Scientific Advisory Board therefore asked RIVM to arrange for an international review of the research report.

To that end, RIVM contacted reviewers from three prominent institutes who are experienced in risk assessment within regulatory frameworks. Reviewers from the United States Environmental Protection Agency (US-EPA) (on personal title), the German Bundesinstitut für Risikobewertung (BfR) and the European Chemicals Agency (ECHA) assessed the report and provided their findings. RIVM is very appreciative of the expert response.

The conclusions from these reviews largely echo the debate on rubber granulate in society and are an important reflection on the work done by RIVM. These reviews assist us in ongoing discussions with our fellow risk assessors and the Ministries that commission our work. The original summaries of the reviews <link> have been posted on the RIVM website.

Primary conclusions from the reviews and response from RIVM
The reviewers were unanimous in stating that the quality of the RIVM study was very good. There was great appreciation for how the study was conducted, certainly considering the time constraints on the study. The reviewers did add a number of comments, some of which had already been addressed in various chapters of the RIVM report <link>.

- One of the significant comments is that the description of the analytical and chemical aspects was limited. We endorse this finding. RIVM outsourced the majority of the analytical procedures to external, certified laboratories. These laboratories conducted their tests according to ISO and NEN standards. These national and international standards specify how the analyses are performed. The laboratories that conducted the tests have the full details.

- Another comment provided by the reviewers is that the RIVM researchers made assumptions in order to facilitate choices during the research process. The question posed by the Minister of Health, Welfare and Sport and the time frame in which her question had to be answered led RIVM to opt for an evaluation of the actual (current) situation, rather than a preventive/regulatory risk assessment that is carried out for example in the case of product authorisation. An evaluation of the risk in an actual situation conducted at the time of exposure, in order to determine whether the exposure level is within acceptable limits. In a preventive/regulatory risk assessment, safe levels are derived and all substances are considered in great detail. RIVM opted for a prioritisation strategy in combination with the assumption of a worst-case scenario for exposure. In other words, we used the highest measured concentrations and an extreme level of contact. Moreover, we focused on the substances that are of very high concern (i.e. substances that may pose serious health risks). The aim of the research was to answer the question whether playing sports on synthetic turf pitches with rubber granulate poses health risks.

- The reviewers from ECHA and EPA endorse the RIVM response to the question of whether playing sports on rubber granulate poses a health risk in this actual situation. The reviewer from BfR notes that in the light of several uncertainties, many of which are due to the extremely short time available for answering the question asked by the Minister of Health, Welfare and Sport, further research would be needed in order to gain more certainty. However, considering the task of assessing the risks from rubber turf pitches as a basis for decisions on immediately required actions, the German reviewer confirms that the RIVM research results are substantial enough and can be accepted as a preliminary, indicative assessment.

It is clear that there are different views on the desirability of playing sports on rubber granulate, not only in the social but also in the scientific field. The RIVM report on rubber granulate can be used by parties in society for making an assessment whether or not to use rubber granulate. A consideration in which besides the health aspects also environmental aspects, costs, the perception of risks of citizens and social acceptance play a role. These are not covered in the report and it is up to the competent authorities to weigh/assess these aspects. Naturally, there are many aspects that can be further investigated, also in an international context. RIVM has already indicated that 'the book on rubber granulate' cannot be closed. We follow the discussions and new studies on the effects of rubber granules on health. We have carried out a risk assessment of the current situation and concluded that playing sports on rubber granulate is safe, as far as the effects of rubber granulate on health are concerned. The effect of these substances on human health is virtually negligible. In addition to the results on the health effects, two topics emerged that RIVM continued to implement in 2017 and 2018. In the 2016 study, the environmental risks of rubber granulate were not taken into account, but RIVM did (again) point to these environmental risks. Moreover, there were many questions from society about the environmental aspects of synthetic turf fields with rubber infill. For this reason, RIVM submitted a research proposal to the Ministry of Infrastructure and Public Works in mid-2017. This led to the commission for an exploratory environmental study in which RIVM maps to what extent rubber granulate as infill affects the environment. The results of this research are expected to be public by mid-2018. Secondly, it emerged that the limit value for PAHs in rubber granulate is high. If the concentration of PAHs is actually as high as the standard allows, then a safe level cannot be guaranteed. That is why RIVM, together with ECHA, has started a process to establish a new limit value.

We have also repeated a number of the experiments originally conducted in the study, particularly the experiments on migration into gastrointestinal fluids. These data were in line with the experiments conducted previously. The supplementary data will be published on the website.

Annex: Summaries of the reviewers

Summary from the reviewer of EPA (The comments provided are those of the reviewer and do not present any official position):
The overall assessment of the scientific quality of the study and the approach taken is very good. The assessment takes into account the short-time frame for the sampling, analysis and report development that was required. The rationale for this assessment includes:

- The large number of fields sampled.
- The chemical analyses performed were comprehensive and included some bioaccessibility measurements based on chemical- and route-specific considerations;
- The exposure assessment is based on default assumptions as there was not sufficient time to observe or make exposure measurements. The assessment used assumptions that are *presumed* to be biased on the conservative end, i.e., likely to overestimate exposure. However, the specifics of any actual scenario may not substantiate this assumption.
- The toxicity assessment was based on literature values for a limited set of chemicals identified as being above some regulatory threshold. This is a standard approach. However, it assumes that only those chemicals that are known are of potential concern. An effort was made to address cumulative effects.

The overall conclusion of negligible risk is a policy decision based on comparison of results of carcinogenic evaluation to a 1 in a million excess cancer for the scenarios evaluated. It is acknowledged that use of the fields is at the discretion of "users". Continued review for new information is appropriate to adjust assumptions, as relevant.

The RIVM scientists and the authors of the report are to be highly commended for the completion of this major study in such a short time frame. The sampling and analysis of 100 football pitches for rubber granulates represents the largest study of its kind to date. The completion of the evaluation of potential risk associated with the materials in rubber granulates within a few months is noteworthy.

Summary from the reviewer of ECHA
The RIVM was asked to determine whether playing sports on synthetic turf pitches with an infill of rubber granulate is safe. In a similar way to ECHA, RIVM compared the results of the concentrations of substances found in rubber granules with the exposures generated from a number of different exposure scenarios developed for the purpose of the assessment. These elements were then compared to determine if there was a health risk for players. The key difference between ECHA and RIVMs methodology was that RIVM sampled 100 pitches to determine the concentrations and migration/evaporation of substances from the rubber granules. ECHA used results from the literature, including the data from the RIVM sampling.
The sampling methods used by RIVM were reported in Part A of the Scientific Background information. One hundred pitches were randomly selected from a list mainly provided by the Dutch Football Association (KNVB) and 6 samples taken from each field. From some fields additional samples were taken to be analysed by separate laboratories for quality checking and for separate migration/evaporation analysis. The sampling and measurement techniques are not all specified in relevant legislation or standards but the methods undertaken seem reasonable and the results reliable, given the checks carried out by TNO for PAHs and phthalates.
Some samples were taken from pitches using granules from rubber products other than tyres and these were not explicitly included in the assessment. On page 24 of the report it was stated that the concentrations of substances do not substantially differ from those from the samples with SBR rubber, except in the samples from two of the nine pitches where high levels of phthalates were found. However, it is not clear from the report why

these were treated differently from other samples as the scope of the investigation was on rubber granules used in synthetic turf. As 9% of the fields had 'materials other than rubber granules from car tyres' this could mean up to 170 pitches in the Netherlands alone (given the reported 1900 pitches). The reasons for this exclusion could be better explained.
The method used by RIVM to select substances for further investigation is described in the report and is considered reasonable. However, it may have been useful to further identify substances in the screening tests that were not fully characterised. Nonetheless, ECHA acknowledges the time constraints for the RIVM investigation.
A number of substances (including PAHs, phthalates and benzothiazoles, phenols and metals) were selected for the hazard assessment. These were similar to the substances ECHA identified for further investigation, even though ECHA used a slightly different approach.
Similarly to ECHA, the RIVM used the BMDL10 derived by EFSA (2008)1 as the point of departure for the PAHs. For the other substances, a DNEL (or other health based limit of non-threshold substances e.g. lead) was identified to take forward in the risk assessment. These DNELs/thresholds seem reasonable and are in line with those used in the ECHA report. Regarding the DNEL for cobalt, the RIVM report does not discuss if the conclusion of RAC that 5 soluble cobalt salts2 have a non-threshold mode of action was considered. Depending on the species of cobalt present in rubber granules the conclusions of RAC may or may not be relevant.
In the RIVM report, 5 Exposure scenarios were prepared: children aged 6 or under; goalkeepers aged 7; children aged 11-18 and adults. ECHA developed similar Exposure Scenarios with some different boundaries related to age: children aged 3-6; children aged 6-11; goalkeepers aged 6-11; children aged 11-18; adult professionals and adult professional goalkeepers. In addition, ECHA developed an exposure scenario for workers installing or maintaining the pitches.
The parameters used in developing the exposure scenarios were very similar between the RIVM and ECHA reports. However, some parameters differed, for example the PM10 value used to estimate inhalation exposure (12 µg/m3 in the RIVM report vs 40 µg/m3 used in the ECHA report) and the direct ingestion values (0.05 g/event for children under 11 and 0.01 for adults in the ECHA report vs 0.2 g/event for children under 11 and 0.05 for adults in the RIVM report). The latter difference was significant as oral exposure is the biggest contributor to the risk. It is acknowledged that the lower amount of granules that ECHA assumed to be ingested by players is not based on concrete evidence. Overall, the Exposure Scenarios used in the RIVM report seem reasonable.
For the PAHs, the total excess risk calculated by RIVM for outfield players and goalkeepers was 9.42E-07 and 2.44E-06 respectively. ECHA calculated for goalkeepers a lifetime excess risk of 7.5E-07 and for outfield players 7.73E-07. These are very similar results. For the other substances in rubber granules that were assessed, RIVM calculated RCRs < 1 with the exception of exposure to lead of children under 7. The reasoning given why the lead exposure was not significant was plausibly explained and was related to the amount of granules ingested in reality and if the total amount released from the ingested granules was available for absorption.
One further point was that both reports did not consider in detail any risks from the synthetic turf itself (the artificial grass blades and backing) and whether substances may leach from the turf to the granules or give rise to direct exposure themselves.
Overall I found the report was of good scientific quality given the constraints placed on you.

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1 Polycyclic Aromatic Hydrocarbons in Food. Scientific Opinion of the Panel on Contaminants in the Food Chain Adopted on 9 June 2008: available at [HYPERLINK "http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/724.pdf"].

2 Establishing a reference dose response relationship for carcinogenicity of five cobalt salts. RAC. 2016. Available from: [HYPERLINK "https://echa.europa.eu/documents/10162/13563/rac_agreement_cobalt_salt_en.pdf/43762b12-5e8f-457a-9858-f5a4737c2e00"].

Summary from the reviewer of BfR:

BfR´s peer review reveals that overall the report is well-written and the approach chosen by RIVM is conceptually reasonable and sound. The report has a high scientific standard and constitutes a remarkable scientific achievement. While putting the theoretical approach into practice a number of assumptions and decisions had to be employed at each step. Some of these introduced a significant level of uncertainty into the assessment.

The main issues raised by BfR are:

- The scientific quality of the report as such is generally very high, with transparent and concise description of investigation details. In certain parts, however, in particular regarding the analytical methodology, several details are missing such that the reliability of some of the analytical results cannot be judged.
- Due to the nature of the strategy for prioritisation, sampling and analysis it cannot be excluded that relevant groups of rubber granulate constituents might have been missed or that their content and/or migration have been underestimated, potentially leading to their exclusion from further risk assessment.
- The assessment was targeted on CMR substances only. The number of established rub-ber granulate constituents to be considered for further health risk assessment might have been higher, if their selection had been performed based on DNELs/DMELs rather than on CLP GCLs/SCLs and official SVHC status.
- Leaching and migration of hazardous substances from rubber granulate may have been underestimated due to the migration methodology employed, at least for the PAHs.
- For the inhalation route the reported data base, notably on dust exposure, is very small.
- Several potentially exposed groups such as small children playing at the pitch and per-sons engaged with infill and with maintenance activities were not included in the assessment due to a lack of time.
- The epidemiological methods used to investigate a potential link between synthetic turfs and leukaemia in children and adolescents may have more limitations than acknowledged in the report.

BfR recognises that many of these uncertainties are due to the extremely short time available for this indicative risk assessment. However, in light of these uncertainties BfR finds that the central statement of the report, i.e. "health risk virtually negligible" is currently not sufficiently backed up by the investigations undertaken so far. Further investigations are needed, some of which are already suggested in the report itself in order to gain more certainty.
Considering the task of assessing the risks from rubber turf pitches as a basis for decisions about immediately required actions, the results of the report are substantial enough and can be accepted as a preliminary, indicative assessment.